

89. A pharmaceutical composition in unit dose form of claim 82 wherein the composition is associated with a pharmaceutically acceptable excipient.

90. A pharmaceutical composition in unit dose form of claim 89 wherein the unit dose is a tablet.

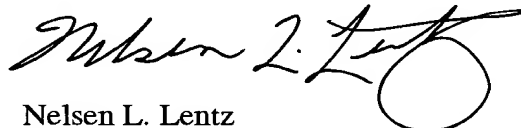
91. A pharmaceutical composition in unit dose form of claim 89 wherein the unit dose is a capsule.

REMARKS

Attached herewith, pursuant to 37 C.F.R. § 1.173(c), is a chart, at Appendix A, providing the status of all patent claims and of all added claims. Further included in the chart, pursuant to 37 C.F.R. § 1.173(c), is an indication of the passages in the originally filed application where, at the very least, the claims find support. In addition, a clean set of all pending claims, original and newly added, are provided for the convenience of the Examiner at Appendix B. It is respectfully submitted that entry of the amendments submitted herewith introduce no new matter to the reissue application.

It is respectfully submitted that the reissue application is now in order for allowance.

Respectfully submitted,



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APPENDIX A -

**STATUS OF CLAIMS AND SUPPORT FOR CLAIM CHANGES PURSUANT TO 37
C.F.R. § 1.173(c)**

<u>Claim</u>	<u>Status</u>	<u>Indication of Support in the Disclosure</u>
1	pending	Original patent claim
2	pending	Original patent claim
3	pending	Original patent claim
4	pending	Original patent claim
5	pending	Original patent claim
6	pending	Original patent claim
7	pending	Original patent claim
8	pending	Original patent claim
9	pending	Original patent claim
10	pending	Original patent claim
11	pending	Original patent claim
12	pending	Original patent claim
13	pending	Original patent claim
14	pending	Original patent claim
15	pending	Original patent claim
16	pending	Original patent claim
17	pending	Original patent claim
18	pending	Original patent claim
19	pending	Original patent claim
20	pending	Original patent claim
21	pending	Original patent claim
22	pending	Original patent claim
23	pending	Original patent claim
24	pending	Original patent claim
25	pending	Original patent claim

26	pending	Original patent claim
27	pending	Original patent claim
28	pending	Original patent claim
29	pending	Original patent claim
30	pending	Original patent claim
31	pending	Original patent claim
32	pending	Original patent claim
33	pending	Original patent claim
34	pending	Original patent claim
35	pending	Original patent claim
36	pending	Original patent claim
37	pending	Original patent claim
38	pending	Original patent claim
39	pending	Original patent claim
40	pending	Original patent claim
41	pending	Original patent claim
42	pending	Original patent claim
43	pending	Original patent claim
44	pending	Original patent claim
45	pending	Column 1, lines 65-67 and column 2, line 1 describe a preferred composition is a weight ratio of olanzapine to Drug Useful in the Treatment of Pain of about one(1) part olanzapine to about one (1) to about hundred (100) parts Drug Useful in the Treatment of Pain. Column 6, lines 16-19 provides further support for the composition of added claim 45.
46	pending	Column 2, lines 1-4 describe an especially preferred ratio of about one part olanzapine (1) to from about one (1) to about thirty (30) parts Drug Useful in the Treatment of Pain. Column 6, lines 19-22 provides further support for the composition of added claim 46.
47	pending	Column 2, lines 4-6 describe a further preferred ratio which may be about one part olanzapine to from about one (1) to about ten (10) parts Drug useful in the Treatment of Pain. Column 6, lines 22-24 provides further support for the composition of added claim 47.

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68	pending	Column 7, lines 31-34 disclose that typical compositions include olanzapine or a pharmaceutically acceptable acid addition salt thereof and one or more Drug Useful in the Treatment of Pain associated with a pharmaceutically acceptable excipient.
69	pending	Column 7, lines 31-36 disclose that the compositions may be enclosed in a carrier.
70	pending	Column 8, line 7 discloses the composition is generally dispensed in unit form. In addition, column 2, lines 4-6 describe a preferred ratio of olanzapine to Drug in the composition which may be about one part olanzapine to from about one (1) to about ten (10) parts Drug. Column 6, lines 22-24 provides further support for the composition of added claim 70. Furthermore, column 5, lines 17-25 disclose Tylenol #3, tricyclic antidepressants (for example desipramine, imipramine, amytriptiline, nortriptyline), anticonvulsants (for example, carbamazepine, gatapentine, valproate), serotonin reuptake inhibitors (for example, fluoxetine, paroxetine, citalopram, sertraline), mixed serotonin-norepinephrine reuptake inhibitors (for example venlafaxine, duloxetine), serotonin receptor agonists and antagonists, cholinergic (muscarinic and nicotinic) analgesics, and neurokinin antagonists.
71	pending	Column 5, line 17 discloses Tylenol #3.
72	pending	Column 5, lines 18-19 disclose tricyclic antidepressants (for example desipramine, imipramine, amytriptiline, nortriptyline).
73	pending	Column 5, line 18 discloses desipramine.
74	pending	Column 5, line 18 discloses imipramine.
75	pending	Column 5, line 18 discloses amytriptiline.
76	pending	Column 5, line 19 discloses nortriptyline.
77	pending	Column 5, lines 19-20 disclose anticonvulsants (for example, carbamazepine, gatapentine, valproate).
78	pending	Column 5, line 19 discloses carbamazepine.
79	pending	Column 5, line 20 discloses gatapentine.
80	pending	Column 5, line 20 discloses valproate.
81	pending	Column 5, lines 20-21 disclose serotonin reuptake inhibitors (for example, fluoxetine, paroxetine, citalopram, sertraline).
82	pending	Column 5, line 21 discloses fluoxetine.
83	pending	Column 5, line 21 discloses paroxetine.

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84	pending	Column 5, line 21 discloses citalopram.
85	pending	Column 5, line 21 discloses sertraline.
86	pending	Column 5, lines 22-23 disclose mixed serotonin-norepinephrine reuptake inhibitors (for example venlafaxine, duloxetine).
87	pending	Column 5, line 23 discloses venlafaxine.
88	pending	Column 5, lines 23 discloses duloxetine.
89	pending	Column 7, lines 31-34 disclose that typical compositions are associated with a pharmaceutically acceptable excipient.
90	pending	Column 8, lines 1-3 disclose that tablets are particularly suitable for oral application.
91	pending	Column 7, lines 31-36 disclose that the carrier may be a capsule.

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APPENDIX B – CLEAN SET OF ALL PENDING CLAIMS

1. A composition for treating pain comprising olanzapine or a pharmaceutically acceptable salt or solvate thereof; and one or more Drug Useful in the Treatment of Pain in a weight ratio of from about one part olanzapine to from about one (1) part to about one thousand (1000) parts Drug Useful in the Treatment of Pain.
2. A composition of claim 1 wherein the Drug Useful in the Treatment of Pain is an NSAIDS.
3. A composition of claim 2 wherein the NSAIDS is selected from the group consisting of aspirin, indomethacin, ibuprofen, naproxen, fenoprofen, tolmetin, sulindac, meclofenamate, keoprofen, piroxicam, flurbiprofen, and diclofenac or a pharmaceutically acceptable salt thereof.
4. A composition of claim 1 wherein olanzapine is Form II olanzapine polymorph having a typical x-ray diffraction pattern as follows, wherein d represents the interplanar spacing:

d
10.2689
8.577
7.4721
7.125
6.1459
6.071
5.4849
5.2181
5.1251
4.9874
4.7665
4.7158
4.4787
4.3307
4.2294
4.141
3.9873
3.7206
3.5645
3.5366
3.3828
3.2516
3.134

3.0848
3.0638
3.0111
2.8739
2.8102
2.7217
2.6432
2.6007.

5. A composition of claim 4 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of aspirin, ibuprofen, and naproxen.

6. A composition of claim 1 wherein the weight ratio of olanzapine to Drug Useful in the Treatment of Pain is from about one part olanzapine to from about one (1) to about one hundred (100) parts Drug Useful in the Treatment of Pain.

7. A composition of claim 6 wherein the weight ratio is from about one part olanzapine to from about one (1) to about thirty (30) parts Drug Useful in the Treatment of Pain.

8. A composition of claim 7 wherein the weight ratio is from about one part olanzapine to from about one (1) to about ten (10) parts Drug Useful in the Treatment of Pain.

9. A composition of claim 8 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of morphine, acetaminophen, ibuprofen, and diclofenac.

10. A composition of claim 1 wherein the Drug Useful in the Treatment of Pain is an opioid compound.

11. A composition of claim 4 wherein the Drug Useful in the Treatment of Pain is an opioid compound.

12. A composition of claim 7 wherein the Drug Useful in the Treatment of Pain is an opioid compound.

13. A composition of claim 10 wherein the opioid compound is selected from the group consisting of morphine, codeine, meperidine, methadone, propoxyphene, levorphanol, hydromorphone, oxymorphone, oxycodone, brompton's cocktail, pentazocine, butorphanol, nabuphine, and buprenorphine.

14. A composition of claim 13 wherein the opioid compound is selected from the group consisting of morphine, oxymorphone, oxycodone, hydromorphone, codeine, and methadone.

15. A composition of claim 1 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of Tylenol #3, tricyclic antidepressants (for example desipramine, imipramine, amitriptyline, nortriptyline), anticonvulsants (for example, carbamazepine, gabapentin, valproate), and serotonin reuptake inhibitors (for example, fluoxetine, paroxetine, citalopram, sertraline), mixed serotonin-norepinephrine reuptake inhibitors (for example venlafaxine, duloxetine), serotonin receptor agonists and antagonists, cholinergic (muscarinic and nicotinic) analgesics, and neurokinin antagonists.

16. A composition of claim 4 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of Tylenol #3, tricyclic antidepressants, anticonvulsants, and serotonin reuptake inhibitors, mixed serotonin-norepinephrine reuptake inhibitors analgesics, and neurokinin antagonists.

17. A composition of claim 16 wherein the Drug Useful in the Treatment of Pain is a tricyclic antidepressant.

18. A composition of claim 1 wherein the Drug Useful in the Treatment of Pain is an alpha adrenergic compound.

19. A composition of claim 18 central alpha-adrenergic active compound is Clonidine or a pharmaceutically acceptable salt thereof.

20. A composition of claim 4 wherein the Drug Useful in the Treatment of Pain is an alpha adrenergic compound.

21. A composition of claim 7 wherein the Drug Useful in the Treatment of Pain is an alpha adrenergic compound.

22. A composition of claim 1 wherein the composition can provide a synergistic analgesic effect.

23. A composition for treating pain comprising olanzapine, or a pharmaceutically acceptable salt or solvate thereof; and ibuprofen, or a pharmaceutically acceptable salt thereof, in a weight ratio of about one part olanzapine to from about one (1) to about one thousand (1000) parts ibuprofen.
24. A composition of claim 23 wherein the olanzapine is Form II olanzapine polymorph.
25. A composition of claim 23 wherein the weight ratio is about one part olanzapine to from about one (1) to about one hundred (100) parts ibuprofen.
26. A composition of claim 23 wherein the weight ratio is about one part olanzapine to from about one (1) to about thirty (30) parts ibuprofen.
27. A composition of claim 26 wherein the weight ratio is about one part olanzapine to from about one (1) to about ten (10) parts ibuprofen.
28. A method for treating pain comprising administering an analgesic dose of a composition comprising olanzapine or a pharmaceutically acceptable salt or solvate thereof; and one or more Drug Useful in the Treatment of Pain in a weight ratio of olanzapine to Drug Useful in the Treatment of Pain of from about one part olanzapine to from about one (1) to about one thousand (1000) parts Drug Useful in the Treatment of Pain.
29. A method of claim 28 wherein the Drug Useful in the Treatment of Pain is an NSAIDS.
30. A method of claim 28 wherein the weight ratio of olanzapine to Drug Useful in the Treatment of Pain is from about one (1) part olanzapine to from about one (1) to about one hundred (100) parts Drug Useful in the Treatment of Pain.
31. A method of claim 28 wherein the weight ratio of olanzapine to Drug Useful in the Treatment of Pain is from about one (1) part olanzapine to from about one (1) to about thirty (30) parts Drug Useful in the Treatment of Pain.

32. A method of claim 28 wherein olanzapine is Form II olanzapine polymorph having a typical x-ray diffraction pattern as follows, wherein d represents the interplanar spacing:

d
10.2689
8.577
7.4721
7.125
6.1459
6.071
5.4849
5.2181
5.1251
4.9874
4.7665
4.7158
4.4787
4.3307
4.2294
4.141
3.9873
3.7206
3.5645
3.5366
3.3828
3.2516
3.134
3.0848
3.0638
3.0111
2.8739
2.8102
2.7217
2.6432
2.6007

33. A method of claim 28 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of alpha adrenergic compounds and opioid compounds.

34. A method of claim 28 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of Tylenol #3, tricyclic antidepressants, anticonvulsants, and serotonin reuptake inhibitors, mixed serotonin-norepinephrine reuptake inhibitors analgesics, and neurokinin antagonists.

35. A method of claim 28 wherein pain is neuropathic pain.
36. A method of claim 28 wherein pain is nociceptive pain.
37. A method of claim 28 wherein the pain is acute pain.
38. A method for treating pain comprising administering an analgesic dose of a composition comprising olanzapine, or a pharmaceutically acceptable salt or solvate thereof, and ibuprofen, or a pharmaceutically acceptable salt thereof, in a weight ratio of about one part olanzapine to from about one (1) to about one thousand (1000) parts ibuprofen.
39. A method of claim 38 wherein the olanzapine is Form II olanzapine polymorph.
40. A method of claim 38 wherein the weight ratio of olanzapine to ibuprofen is about one (1) part olanzapine to from about one (1) to about one hundred (100) parts ibuprofen.
41. A method of claim 40 wherein the weight ratio of olanzapine to ibuprofen is about one (1) part olanzapine to from about one (1) to about thirty (30) parts ibuprofen.
42. A method of claim 38 wherein the pain is neuropathic pain.
43. A method of claim 38 wherein the pain is nociceptive pain.
44. A method of claim 38 wherein the pain is acute pain.
45. A pharmaceutical composition comprising olanzapine or a pharmaceutically acceptable salt or solvate thereof and one or more Drugs Useful in the Treatment of Pain in a weight ratio of about one (1) part olanzapine to about one (1) to about one hundred (100) parts Drug Useful in the Treatment of Pain.
46. A pharmaceutical composition of claim 45 wherein the weight ratio of olanzapine to Drug Useful in the Treatment of Pain is about one (1) part olanzapine to about thirty (30) parts Drug Useful in the Treatment of Pain.
47. A pharmaceutical composition of claim 45 wherein the weight ratio of olanzapine to Drug Useful in the Treatment of Pain is about one (1) part olanzapine to about ten (10) parts Drug Useful in the Treatment of Pain.
48. A pharmaceutical composition of claim 45 wherein the weight ratio of olanzapine to Drug Useful in the Treatment of Pain is about one (1) part olanzapine to about three (3) parts Drug Useful in the Treatment of Pain.

49. A pharmaceutical composition of claim 45 wherein the Drug Useful in the Treatment of Pain is selected from the group consisting of Tylenol #3, tricyclic antidepressants (for example desipramine, imipramine, amitriptyline, nortriptyline), anticonvulsants (for example, carbamazepine, gabapentine, valproate), serotonin reuptake inhibitors (for example, fluoxetine, paroxetine, citalopram, sertraline), mixed serotonin-norepinephrine reuptake inhibitors (for example venlafaxine, duloxetine), serotonin receptor agonists and antagonists, cholinergic (muscarinic and nicotinic) analgesics, and neurokinin antagonists.

50. A pharmaceutical composition of claim 49 wherein the Drug Useful in the Treatment of Pain is Tylenol #3.

51. A pharmaceutical composition of claim 49 wherein the Drug Useful in the Treatment of Pain is a tricyclic antidepressant.

52. A pharmaceutical composition of claim 51 wherein the tricyclic antidepressant is desipramine.

53. A pharmaceutical composition of claim 51 wherein the tricyclic antidepressant is imipramine.

54. A pharmaceutical composition of claim 51 wherein the tricyclic antidepressant is amitriptyline.

55. A pharmaceutical composition of claim 51 wherein the tricyclic antidepressant is nortriptyline.

56. A pharmaceutical composition of claim 49 wherein the Drug Useful in the Treatment of Pain is an anticonvulsant.

57. A pharmaceutical composition of claim 56 wherein the anticonvulsant is carbamazepine.

58. A pharmaceutical composition of claim 56 wherein the anticonvulsant is gabapentine.

59. A pharmaceutical composition of claim 56 wherein the anticonvulsant is valproate.

60. A pharmaceutical composition of claim 49 wherein the Drug Useful in the Treatment of Pain is a serotonin reuptake inhibitor.

61. A pharmaceutical composition of claim 60 wherein the serotonin reuptake inhibitor is fluoxetine.

62. A pharmaceutical composition of claim 60 wherein the serotonin reuptake inhibitor is paroxetine.

63. A pharmaceutical composition of claim 60 wherein the serotonin reuptake inhibitor is citalopram.

64. A pharmaceutical composition of claim 60 wherein the serotonin reuptake inhibitor is sertraline.

Sub
P3
65. A pharmaceutical composition of claim 49 wherein the Drug Useful in the Treatment of Pain is a mixed serotonin-norepinephrine reuptake inhibitor.

66. A pharmaceutical composition of claim 65 wherein the mixed serotonin-norepinephrine reuptake inhibitor is venlafaxine.

67. A pharmaceutical composition of claim 65 wherein the mixed serotonin-norepinephrine reuptake inhibitor is duloxetine.

68. A pharmaceutical composition of claim 49 wherein the composition is associated with a pharmaceutically acceptable excipient.

69. A pharmaceutical composition of claim 68 wherein the composition is enclosed within a carrier.

Sub
A3
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70. A pharmaceutical composition in unit dose form comprising olanzapine or a pharmaceutically acceptable salt or solvate thereof; and a Drug selected from the group consisting of Tylenol #3, tricyclic antidepressants (for example desipramine, imipramine, amitriptyline, nortriptyline), anticonvulsants (for example, carbamazepine, gabapentine, valproate), serotonin reuptake inhibitors (for example, fluoxetine, paroxetine, citalopram, sertraline), mixed serotonin-norepinephrine reuptake inhibitors (for example venlafaxine, duloxetine), serotonin receptor agonists and antagonists, cholinergic (muscarinic and nicotinic) analgesics, and neurokinin antagonists wherein the weight ratio of olanzapine to compound is about one (1) part olanzapine to about ten (10) parts compound.

71. A pharmaceutical composition in unit dose form of claim 70 wherein the Drug is Tylenol #3.

72. A pharmaceutical composition in unit dose form of claim 70 wherein the Drug is a tricyclic antidepressant.

73. A pharmaceutical composition in unit dose form of claim 72 wherein the tricyclic antidepressant is desipramine.

74. A pharmaceutical composition in unit dose form of claim 72 wherein the tricyclic antidepressant is imipramine.

75. A pharmaceutical composition in unit dose form of claim 72 wherein the tricyclic antidepressant is amitriptyline.

76. A pharmaceutical composition in unit dose form of claim 72 wherein the tricyclic antidepressant is nortriptyline.

77. A pharmaceutical composition in unit dose form of claim 70 wherein the Drug is an anticonvulsant.

78. A pharmaceutical composition in unit dose form of claim 77 wherein the anticonvulsant is carbamazepine.

79. A pharmaceutical composition in unit dose form of claim 77 wherein the anticonvulsant is gabapentine.

80. A pharmaceutical composition in unit dose form of claim 77 wherein the anticonvulsant is valproate.

81. A pharmaceutical composition in unit dose form of claim 70 wherein the Drug is a serotonin reuptake inhibitor.

82. A pharmaceutical composition in unit dose form of claim 81 wherein the serotonin reuptake inhibitor is fluoxetine.

83. A pharmaceutical composition in unit dose form of claim 81 wherein the serotonin reuptake inhibitor is paroxetine.

84. A pharmaceutical composition in unit dose form of claim 81 wherein the serotonin reuptake inhibitor is citalopram.

85. A pharmaceutical composition in unit dose form of claim 81 wherein the serotonin reuptake inhibitor is sertraline.

86. A pharmaceutical composition in unit dose form of claim 70 wherein the Drug is a mixed serotonin-norepinephrine reuptake inhibitor.

87. A pharmaceutical composition in unit dose form of claim 86 wherein the mixed serotonin-norepinephrine reuptake inhibitor is venlafaxine.

88. A pharmaceutical composition in unit dose form of claim 86 wherein the mixed serotonin-norepinephrine reuptake inhibitor is duloxetine.

89. A pharmaceutical composition in unit dose form of claim 82 wherein the composition is associated with a pharmaceutically acceptable excipient.

90. A pharmaceutical composition in unit dose form of claim 89 wherein the unit dose is a tablet.

91. A pharmaceutical composition in unit dose form of claim 89 wherein the unit dose is a capsule.